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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,806	05/05/2005	Hashime Kanazawa	2005_0741A	8202

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EXAMINER	
DESAI, RITA J	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
02/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,806	KANAZAWA ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6, 8-15, 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-15, 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

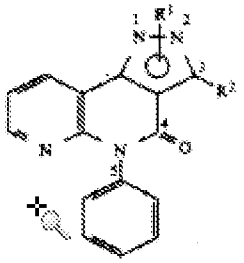
Claims 1-6, 8-15, 19-24 are pending.

The foreign priority date has been noted and acknowledged.

The rejection of the claims 6,8-9, 13-15 and 19-24 under 35 USC 112 second has been withdrawn as applicants have amended the claims.

The rejection of claims 1-24 (now 1-6, 8-15, 19-24) under 35 USC 103 over EP 0526840 and US 5281610 however still stands. Applicants declaration does have some data for one compound. Just the phenyl.

The prior art also has thienyl group and an alkyl chain . see below.



wherein R^1 is represents hydrogen, lower alkyl, aralkyl, or substituted or unsubstituted aryl, R^2 represents hydrogen, lower alkyl, thienyl, substituted or unsubstituted aryl, hydroxy or amino, or a pharmaceutically acceptable salt thereof.

The compound possesses antiinflammatory effect, immunosuppressive effect, broncho-dilatory effect and hair growth-stimulative effect.

The reference also teaches that they have bronco dilatory effect. Applicants claims are also drawn to the same treatment, "bronchial asthma" . Applicants argument that the A group with

the linkage is a distinct feature for the acquisition of PDE IV inhibitory activity is not understood. The prior art compounds have the same activity as bronco dilators.
Applicants claims are also drawn to treating asthma and such which are also treated by bronchodilators.
Applicants arguments with respect to the advantages is also not convincing. The Sazuki reference may be just silent as to the type of inhibition, but it does treat the same disorder, Broncodilation, which is what is required to treat a number of bronchial disorders.

Applicants further argue that it has an unexpected increase in PDE IV inhibition
Applicants declaration does not compare all the closest art compounds and is not convincing.

WO 01/42244 and EP 1236 725, Aotsuka et al discloses the A group on a similar naphthyridin -2(1H)-one derivative. These are PDE IV inhibitors too.
These references have a methylene group with the A substitutent. (these references were provided in the IDS and are used only to overcome applicants arguments that the novelty of the activity is due to the CH2-A group)
Thus motivation to modify the US '610 compounds can also come from the teaching of WO '244 and '725 which have the substitutent similar to the one at the 3 position.
Thus the rejection still stands.

The rejection of the claims 1-24 (now claims 1-6, 8-15, 19-24) under 35 USC 103 over the combination of US 5281, 610 and of JP 6-100561 has been withdrawn .

The rejection really can stand alone on US '610 as given above.

The rejection of claims 1-24 (now 1-6, 8-15, 19-24) under 35 USC 112 first para has been withdrawn in part.

In part because applicants have deleted the term "prophylaxis" however the claims still contain numerous disorders , ARDS, COPD, pneumonic diseases (not clear which disease is included).

6) The amount of direction provided by the inventor: The inventor provides very little direction in the instant specification. There are no examples that these compounds do in fact treat or have a prophylaxis effect for the above mentioned conditions. Each disease would have to be treated differently with different dose amount. There is no guidance in the specifications as to what the dose would be to treat a certain disorder. Page 32 has a general description of doses which can be in a 1000 fold range. The different diseases would have to be administered differently and applicants have not provided any guidance for the same.

The specification does not provide enough guidance.

Only some PDE IV inhibition data is given in table I page 34, for some of the compounds.

The IC 50 value ranges from .020 to .089. Rolipram a known compound showed . 19 inhibitory activity.

On page 37 , table 2 only 2 compounds were tested 9 and 33 and it was also .16 and .33.

Data for other compounds has not been shown and the activity has not been shown either.

This guidance is not sufficient to indicate that the full scope of the compounds would be able to "treat " all the various disorders effectively.

IN view of applicants arguments that the chain linkages shows unexpected properties , applicants need to provide more guidance as just a difference of a chain can also change the activity (as argued by the applicant).

In view of the unpredictability in the art and the lack of guidance shown it cannot be seen how the claims are enabled to treat all the various disorders.

Conclusion

None of the claims are found to be allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
February 15, 2008

/Rita J. Desai/
Primary Examiner, Art Unit 1625